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KRIEG DEVAULT LLP
ONE INDIANA SQUARE, SUITE 2800
INDIANAPOLIS, IN 46204-2709

EXAMINER	
SWIGER III, JAMES L	

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3733	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-19 and 21-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winslow et al. (Reference U.S Patent 6,083,225) in view of Smith (US Patent 4,862,891) and Orth et al. (US Pub 2002/0002360).

Winslow et al. (herein Winslow) disclose a device capable of performing percutaneous interbody fusion having at least at least one intervertebral disc spacer that is configured for insertion into an intervertebral disc (see Fig. 13) and a tool (82) for delivering the at least one disc spacer (col. 9, lines 13-19). A retractor is used for delivering the at least one disc spacer through one of the dilators to an intervertebral disc space. Winslow also teaches an intervertebral disc spacer that has holes (200) that may be used for bone-growth inducing substances (Col. 3, lines 19-25) and thus the use of a bone matrix substance being part of the kit is implied in its use.

Winslow discloses the claimed invention except for at least one guide needle and a plurality of dilators. Smith disclose a at least one guide needle (33) and a plurality of dilators (36-41) wherein a first dilator has an inner diameter that is slightly larger than an outer diameter of the guide needle, and each dilator having an inner diameter

successively larger than an outer diameter of a previous dilator (see Fig. 7 and see Col. 5, lines 35-45) in order to dilate a passage with increased accuracy and reduced trauma. It would have been obvious to one skilled in the art at the time the invention was made to construct the kit of Winslow having at lest one guide needle and a plurality of dilators in view of Smith, in order to dilate a passage with increased accuracy and reduced trauma.

Winslow discloses the claimed invention except for a package that is sterilized with the claimed instrumentation. Orth et al. teach a kit comprised in a container for holding the various kit components together, typically being a pouch, tray, box, tube, or the like. The box would have at least depressions to hold the tools in place. Additionally the box or container-like structure would inherently have at least a top or bottom surface in a way that would protect the sterized tools.The kit components would be sterilized and maintained to sterility within the packaging [0015]. It would have been obvious to one skill in the art at the time the invention was made to construct the kit of Winslow et al. in view of Orth in order maintain sterility within the package. It is noted that all the components of the claimed invention can inherently be assembled into a kit.

Response to Arguments

Applicant's arguments submitted 2/5/2008 with respect to claims 16-19 and 21-36 have been considered but are considered unpersuasive. It is still held that the combination of Winslow et al. and Smith and Orth et al. disclose the claimed invention. As noted by applicant, performing an interbody spinal fusion can be a complicated procedure, classified as a major surgery with a large incision. There is a desire for a

less invasive procedure that reduces patient trauma. In the claimed invention, a surgical kit is claimed which has an intervertebral spacer used in the spirit of the invention and a device that allows for the insertion of the spacer while permitting minimal trauma to the patient. Winslow discloses the at least one intervertebral disc spacer, whereas Smith teaches the use of a device for "sequential dilation of a tissue opening which avoids the need for surgical cut-down and increases the simplicity and safety of cannula insertion," (Col. 2, lines 19-22). Additionally it is noted that the intervertebral disc spacer is "configured for insertion into an intervertebral space..." and the dilators are "configured for incrementally increasing the height of an intervertebral space." It is understood that the claimed device intends the dilators to aid in the expansion and incremental dilation of the spine. However, as noted above, the limitations of the intervertebral disc spacer and dilators are functionally recited and thus only require the ability to do so. The dilators have the ability to incrementally expand a space, and likewise complement the insertion of the spacer, which requires an incision of appropriate and adequate size. With regards to the "package" it is obvious that a surgical kit be sanitary and have all required components. See above rejection regarding Orth et al. for the teaching of the kit which would protect the sterilized tools.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is (571)272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L SWIGER/
Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733